REMARKS

This Amendment is response to the Office Action dated May 8, 2009. Prior to entry of this Amendment, claims 3,4,6,7,36-44,46,47,49-53,106-117, 121,122,127,128 and 137-168 were pending. This Amendment cancels claims 3,7,47,88,93,119,122,129,132,157 and 159. No new claims have been added.

A Notice of Appeal was filed in connection with this application on August 6, 2009 and was received by the USPTO on August 10, 2009. Accordingly, it is believed that no extension of time is required.

Support for Claim Amendments

The independent claims have now been further amended to call for the ingredient in the first receiving chamber to be an oil ingredient and the ingredients of the second receiving chamber to be solids, with the active ingredient in the second receiving chamber being a solid. Support for the oil ingredient has previously been identified in Applicant's amendment filed on February 12, 2009. This feature has merely been moved from the dependent claims (e.g., claims 157 and 159, now canceled) to the independent claims. Support for all of the ingredients of the second receiving chamber being a solid is found, for example, in paragraph 0049 of the specification, and in the Examples.

The support for the additions made to the claims is exemplary, and additional support is found throughout the specification.

Status of Application

This Amendment is filed with a Request for Continued Prosecution, so that the Examiner can fully consider the changes made to the claims, the arguments made herein, and the accompanying Declaration of the Inventor in support of patentability. Claims 3-4, 6, 36-44, 46, 49-53, 106-118, 120-121, 128, 135, 137-156, 158, and 160-168 are now included in the prosecution after the claim amendments made herein.

The Examiner's consideration of the IDS's submitted on 2/17/09 and 4/20/09 are acknowledged with gratitude.

The Examiner's removal of the prior rejections made under 35 U.S.C. §103(a) as being unpatentable over Nowak et al. in view of Zimmer, or over Nowak et al. in view of Zimmer and Rashid et al. is gratefully acknowledged.

Claim Rejection under 35 U.S.C. § 112

In the Office Action dated May 8, 2009, the Examiner rejected claim 3 under U.S.C. §112, second paragraph, as being indefinite with respect to the phrase "said cap" in line 2. Claim 3 has now been canceled, rendering this rejection moot.

Claim Rejection under 35 U.S.C. §102

In the Office Action, the Examiner rejected claims 6-7, 41-44, 46-47, 49-53, 122, 127, 137-142, 145-146, 161-164 and 167-168 under 35 U.S.C. 102(e) as being anticipated by Bakhshaee et al. (WO 02/07710 A2).

The Examiner's rejection on this basis is respectfully traversed.

The claimed invention is directed to a multi-compartment capsule "wherein (A) said active ingredient of said first receiving chamber is different from said active ingredient of said second receiving chamber and not present in said second receiving chamber..." See, e.g., independent claim 142. The other independent claims presently under consideration (claims 36 and 141) are similarly limited.

Significantly, the Examiner at page 6 of the Office Action states that "Bakhshaee also teaches that is "known to provide double, triple and, sometimes, quadruple therapies for the treatment of many conditions, wherein the inner and outer capsules can be provided in certain, but not all, combinations of solid and soft gel capsules containing the same or different active principles in solid or liquid form" (Page 4, lines 6-13)."

The Examiner has taken this statement from Bakhshaee out of context. This statement is discussing prior capsule technology described on pages 1-4 of the Bakhshaee specification, and is not describing the Bakhshaee invention at all. In fact the quotation cited by the Examiner begins with the phrase "The multiple capsule delivery devices discussed above show that it is known..." It is noteworthy that the Examiner has not relied on any of the "multiple capsule delivery devices discussed above" in making the rejection. However, the Examiner then further acknowledges that Bakhshaee describes the same active principle in the inner and outer capsules (see, e.g., page 6, lines 3 and 15).

Bakhshaee makes it abundantly clear that in the delivery device described therein, the "inner and outer capsules contain the same active principle". See, Bakhshaee at page 5, lines 15-16; page 6, lines 1-2; page 6, lines 20-25; page 8, lines 20-24; page 9, lines 13-19 and lines 21-32; page 10, lines 5-14; page 13, lines 10 – 27; and elsewhere throughout Bakhshaee. The Examiner's attention is directed to page 17 beginning at line 3 and page 18 beginning at line 15, where it is explained that the delivery device of Bakhshaee is intended to provide delivery of a single active principle to more than one site in the GI tract, e.g. by altering the release rate for the different capsules.

A careful examination of the Bakhshaee disclosure has been undertaken, and it is recognized that at page 20, lines 8 – 29, it is stated that the delivery device may comprise further active principles together with the same primary principle: "...For example, the outer capsule 2 may contain a main active principle 3 together with another, second active principle, whereas inner capsule 4 may contain the same main active principle 5 and a further, third active principle, main principles 3 and 5 being the same in the same or different phases..."

It is believed that the claims in their previous form differentiated from Bakhshaee in that it is clear that the claims herein call for the (active) ingredient to be different in each of, e.g., the first and second receiving chambers. For example, claim 141 as presented stated that "said ingredient of said first receiving chamber is different from said ingredient of said second receiving chamber..."; claims 36 and 142 as presented stated that "said active ingredient of said first receiving chamber is different from said active ingredient of said second receiving chamber and not present in said second receiving chamber...". However, in order to advance prosecution, the independent claims have now been revised to clarify that all of the active ingredients of the first receiving chamber are different from the actives in the second receiving chamber.

In particular, claim 36 as currently amended now states: "a first receiving chamber comprising **an active oil ingredient selected from the group consisting of a nutraceutical, a vitamin, and a dietary supplement** in immediate release form; and a second receiving chamber **containing only solid ingredients and** comprising at least one active ingredient in a solid state and formulated in a manner allowing for a time-delayed dissolution and release of said solid **active** ingredient, wherein said active ingredient of said first receiving chamber is different from said **at least one** active ingredient of said second receiving chamber and not present in said second receiving chamber."

Claim 141 as currently amended now states: "wherein **the ingredients** said ingredient of said first receiving chamber is different from **the ingredients** said ingredient of said second receiving chamber."

Claim 142 states: "wherein (A) said active ingredient of said first receiving chamber is different from said active ingredient of said second receiving chamber and not present in said second receiving chamber…" Since claim 142 states the ingredients in singular form, Applicant does not believe that it is necessary to further clarify this claim as the singular tense would encompass any pluralities of ingredients.

In view of the above, it is respectfully submitted that the Examiner's rejection of the claims as anticipated by Bakhshaee under 35 U.S.C. §102(e) has been overcome and should be removed.

Prior Rejections Under 35 USC §103(a)

In the Office Action, the Examiner took the position that claims 3-4 and 37-40 are unpatentable under 35 U.S.C. 103(a) as being unpatenable over Bakhshaee et al. in view of Rashid (U.S. 5,750,143). The Examiner noted that Bakhshaee does not expressly teach a cap comprising a configuration to reduce dead volume space within the first receiving chamber. The Examiner particularly relies upon Rashid as teaching "a controlled release capsule where "although conventionally shaped round caps may be used, the cap is preferably substantially flattened to compared to conventional caps so as to accommodate a tablet whilst retaining the compact nature of the capsule by minimizing dead space in the first volume" (Col. 2, lines 63-67)."

Applicant respectfully traverses the Examiner's rejection. Claim 3 has now been canceled.

First, it is noted that Rashid et al. does not describe a first receiving chamber comprising at least one (active) ingredient in an oil in immediate release form; and a second receiving chamber containing only solid ingredients and comprising at least one active ingredient in a solid state, as required by the claims. Rather, Rashid states that the first and second dosages of pharmaceutically active material (which may be the same or different active material) are generally provided in solid form, such as a tablet (though other known dosages forms are possible, such as powders, granules, pellets, capsules and semi-solid material.". See Rashid at column 2, lines 56-62.

It is noted that the claims in question directed to the lack of dead space require the first receiving chamber, which contains an oil, to have no dead space. Rashid does not address dead space in a receiving chamber containing an oil, and in fact it is believed that Rashid does not contemplate that its final dosage form contain liquid such as oil (see the quotation above, and the specification of Rashid). The Examiner's reliance on particular statements in Rashid (regarding the flattening of the cap in order to accommodate a tablet while minimizing dead space) confirms this.

In view of at least the above arguments, it is respectfully submitted that Rashid does not overcome the deficiencies of Bakhshaee, and that claims 4 and 37-40 are patentable over the combination of Bakhshaee and Rashid.

In the Office Action, the Examiner rejected claims 106 – 117, 121, 128, 143-144, 157 – 160 and 165 – 166 as being unpatentable over Bakhshaee.

The Examiner's rejection of these claims as obvious in view of Bakhshaee is respectfully traversed.

In this regard, the Examiner's attention is directed to Applicant's arguments concerning Bakhshaee presented earlier with respect to the rejection under 35 U.S.C. §102(e). It is respectfully submitted that the claims clearly differentiate from Bakhshaee in that it is clear that the claims herein call for the (active) ingredient to be different in each of, e.g., the first and second receiving chambers, and that there can be no two actives that are the same in both the first and second receiving chambers.

Further, the claims as amended are now limited to the presence of oil in the first receiving chamber, and only solids in the second receiving chamber. Bakhshaee does not hint or suggest this combination. It is noted that dependent claims 157 and 159 (now canceled) were directed to the liquid ingredient in the first chamber comprising an oil. It is respectfully submitted that Bakhshaee does not contemplate an oil as being the sole ingredient(s) of the outer capsule (e.g., first chamber). Bakhshaee briefly mentions the possibility that a lipid or fat can be included with an active ingredient, but therein it is contemplated that the inclusion of the lipid or fat would be as a solvent for the purpose of delivering "the same active principle in a variety of solvents", e.g., an inner capsule containing an aqueous liquid formulation of the active and the outer capsule containing a lipidic formulation of the same active. See, Bakhshaee at page 19, lines 12 – 24. Bakhshaee does not contemplate the oil *itself* as the active ingredient of the outer capsule (or first receiving chamber). Nor does Bakhshaee specifically contemplate an oil in the outer capsule and a solid(s) in the inner capsule (e.g., second receiving chamber).

Therefore, it is respectfully submitted that the claims as amended are not obvious in view of Bakhshaee.

Nevertheless, the pending dependent claims are respectfully submitted to provide further patentable distinctions over Bakhshaee. In this regard, the Examiner's position that the particularly stated active ingredients as recited in the dependent claims would be obvious to try is respectfully traversed. While an "obvious to try" rationale may support a conclusion that a claim would have been obvious where one skilled in the art is choosing from a *finite number* of identified, predictable solutions, with a reasonable expectation of success, in the present case the Examiner has not provided any basis that the stated active ingredients are chosen from a finite

number of identified, predictable solutions. Rather, the stated active ingredients were chosen from an infinite number of active agents from the pharmaceutical, biotechnical, nutraceutical, vitamin , and dietary supplement fields. It is only with the improper use of hindsight that the specific combinations set forth in the claims can be considered under the "obvious to try" standard. In fact, the Examiner has pointed to nothing in Bakhshaee that speaks to particular combinations – and that is because Bakhshaee does not disclose a single particular active agent, let alone any combinations. The Examiner is reminded that the focus of Bakhshaee is entirely upon a delivery device having an inner and outer capsule containing the same active agent. The present claims and specification simply cannot be used as a road map for creating hindsight obviousness.

Declaration of Inventor Fred H. Miller

Submitted herewith as additional evidence of patentability is the Declaration Under 37 CFR 1.132 of Fred H. Miller, the named inventor of the presently considered application. In his Declaration, inventor Miller explains the commercial success associated with the presently claimed invention.

In this regard, the Examiner is reminded that, to the extent needed, rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others." Graham v. John Deere Co., 383 U.S. at 17, 148 USPQ at 467. See also, e.g., In re Piasecki, 745 F.2d 1468, 1473, 223 USPQ 785, 788 (Fed. Cir. 1984) (commercial success). It is only after determining the differences between the subject matter sought to be patented and the prior art, the ordinary skill level in the field, and evaluating the secondary considerations discussed herein, that a determination of the obviousness of the subject matter as a whole, at the time the invention was made, by one of ordinary skill in the art may be made.

It is respectfully submitted that the Miller Declaration demonstrates two secondary considerations – commercial success and the acquiescence of market competitors in obtaining a license for the presently claimed invention from the assignee.

It is noted that the development of the claimed multicompartment formulations did not come about before the filing date of the present application. Indeed, it was only after the technology was licensed that products began to appear in commerce which utilize the claimed technology. It is logical to assume that if the solution to a problem rewarded the problem solver with commercial success and the solution were obvious, then someone would have brought the solution to market to gain the commercial success. In other words, if the invention was obvious, then it is safe to assume that someone else seeking that commercial success would have previously brought it to market.

It is recognized that the commercial success must relate to the applicant's claimed invention and not merely what the application discloses. As stated in MPEP §716.03, an applicant who is asserting commercial success to support its contention of nonobviousness bears the burden of proof of establishing a nexus between the claimed invention and evidence of commercial success.

It is respectfully submitted that the Miller Declaration establishes such a nexus between both the commercial success and licensing of the claimed invention. The Miller Declaration states that there is a license to a third party. More particularly, at paragraph 17 of the Miller Declaration, Mr. Miller states that the assignee and a third party (NUTREX) entered into a license agreement for the claimed invention (referred to in the Miller Declaration as the "INNERCAP Technologies delivery system") and that NUTREX is selling delivery devices using the INNERCAP Technologies delivery system with significant commercial success. In the present case, the commercial success and license is associated with products that are covered by the claims (see Paragraphs 25 and 26 of the Miller Declaration). Furthermore, it is respectfully submitted that the claimed features were responsible for the commercial success of the claimed multicompartment capsules – a comparison can be made between a product which doesn't fall within the present claims (e.g., NUTREX's LIPO® 6 product) and a product which bears the features of the claimed invention (e.g., NUTREX's LIPO® 6X product). It is respectfully submitted that the increase in sales and the recoupment of lost sales brought about by the switch to the claimed technology is not due merely to marketing of the product. If marketing could

have brought about the increased sales, then there existed no reason for NUTREX to bear the cost of changing its product line and pay license fees to the assignee of the present invention. NUTREX would merely have increased its marketing efforts and maintained its previous LIPO 6 product line. Accordingly, it is respectfully submitted that the licensing and commercial success is due to the presently claimed features, and the evidence of nonobviousness is to be accorded substantial weight. See *In re Huang*, 100 F.3d 135, 140, 40 USPQ2d 1685, 1690 (Fed. Cir. 1996).

In addition to the existence of a license for the claimed invention, it is also noteworthy that products utilizing the claimed invention have been featured in GNC advertisements and are arranged at featured locations in GNC stores, such as the cash register counter space which is premium space only offered to the products with the greatest sales potential, as well endcaps. Miller Declaration at paragraph 24.

It is respectfully submitted that the scope of the claims are appropriate with respect to the consideration of commercial success as discussed in the Miller Declaration. The claim language closely follows the commercial products.

In view of the above, and for other reasons, it is respectfully submitted that the Miller Declaration establishes the secondary consideration of commercial success for the presently claimed invention.

Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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